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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,925	12/28/2001	Richard N. Ellison	7610-0040.20	5528

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EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/040,925	Applicant(s) ELLSON ET AL.	
	Examiner Nelson Yang	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 31, 33, 34, 45, 46, 48 and 61-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-30, 32, 35-44, 47 and 49-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 6-11, 31, 33, 34, 45, 46, 48 and 61-82 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/1/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-60, drawn to a device, classified in class 422, subclass 50.
 - II. Claims 61-62, drawn to an apparatus for attaching molecular moieties, classified in class 435, subclass 286.2.
 - III. Claims 63-64, drawn to a method for attaching molecular moieties, classified in class 435, subclass 7.1.
 - IV. Claims 65-73, drawn to an apparatus for assaying a sample, classified in class 435, subclass 287.1.
 - V. Claims 74-82, drawn to a method for assaying a sample, classified in class 436, subclass 55.
1. The inventions are distinct, each from the other because of the following reasons:
2. Inventions I, II, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The apparatus of group I is intended for detecting molecular interactions, and requires an indicator for detecting a condition, whereas the apparatus of group II is intended for attaching molecular moieties, and requires a means for attaching a plurality of molecular moieties to the surface of a substrate, and the apparatus of group IV requires an indicator for applying a sample.

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1. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the apparatus of group I can be made using an ink jet printing method or by electropolymerization, while the process of group III can be used for creating coatings and layers.
2. Inventions I and V; II and III; II and V; III and IV; IV and V; are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group I can be used as a filter for removing molecular moieties from a sample, the product of group II can be used in ink jet printing methods for preparing a coated substrate, the method of group III can be performed using a mask, the product of group IV can be used for detecting environmental conditions, and the method of group V, can be performed using coated particles.
3. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and modes of operation, as well as different effects. The method of group III is directed to attaching molecular moieties to a substrate, while the method of group V is directed toward assaying a sample, and requires the step of detecting for target probe interactions.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for others, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: maximum temperature, minimum temperature, a predetermined water content, a chemical concentration, drawn to claims 6-18; nucleotidic, peptidic, oligomeric, and polymeric probes, drawn to claims 31-34; a disk, tape, well plate, and slide, drawn to claims 45-48.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1-5, 19-30, 35-44, 49-60 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Shelley Eberle on June 10, 2004 a provisional election was made with traverse to prosecute the invention of group 1, and a provisional election with traverse to prosecute the following species: chemical concentration, peptidic probes, and well plate; claims drawn to this election are claims 1-5, 12-30, 32, 35-44, 47, 49-60. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-11, 31, 33-34, 45, 46, 48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

7. With respect to the references crossed out in the IDS, while the references have been considered, they can not be entered, as they have not been published, and are not available to the public.

Claim Rejections - 35 USC § 112

II. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5, 12-30, 32, 35-44, 47, 49-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 recites the limitation of an integrated indicator. It is not entirely clear where the indicator is integrated to, whether it is to the substrate, more specifically the surface of the substrate, to the probes, or to something separate from the substrate.

10. With respect to claim 1-5, 12-18, 52-60, it is unclear if applicants are referring to the same condition, or if there are two separate types of conditions being discussed, namely, interactive conditions involving the probes and targets, such as hybridization and binding reactions, and external conditions, such as environmental conditions like temperature and pH. Since applicant has used the term conditions to describe both of these situations, and further recites an indicator that responds to a condition, it is unclear which condition the indicator is actually responding to, or if the indicator is actually responding to both conditions, or if something else entirely different was meant.

11. Claim 2 recites the limitation of removing the indicator from the condition. However, in claim 1, applicant recited the limitation that the indicator is integrated. If in claim 1, applicant intended for the indicator to be integrated to the substrate, it is unclear if applicant intends to remove the indicator from the substrate, and if so, how applicant would separate the indicator from the substrate.

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12. The term "substantially" in claim 4 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how a response could be substantially permanent, without being permanently detectable. Specifically, since a permanently detectable response would be detectable forever presumably, it is unclear how long a response would need to be detectable before it would be considered substantially permanent.

13. With respect to claim 14, it is not entirely clear what is meant by the limitation that the chemical concentration comprises a pH of about 5 to about 9. It is unclear if applicant intends for the pH of the chemical concentration to be from about 5 to about 9, or if the chemical concentration is actually comprised of a pH of about 5 to about 9.

14. With respect to claims 52-57, it is unclear what probes would be selected. Since it is unclear what the conditions the probes would be exposed to are, it is unclear how a person of ordinary skill in the art would be able to select probes to interact with corresponding targets when exposed to at least one of the plurality of conditions, without knowing what the conditions are. Currently, it is assumed that members of a binding pair would interact with each other under all conditions in the plurality of conditions.

15. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 102

III. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-5, 12-30, 32, 35, 40-44, 47, 49-60, are rejected under 35 U.S.C. 102(b) as being anticipated by Nova et al [US 5,874,214].

With respect to claims 1-4, 24, 25, 30, 32, 35, 40-44, 58, Nova et al teach a device that are a combinations of matrix materials with programmable data storage or recording devices (column 4, lines 55-64) comprising immobilization of proteins and other biomolecules onto solid or liquid supports (column 23, lines 50-55), photodetectors to detect fluorescence and other optical emissions (column 6, lines 25-36), as well as radiation, pH, and PCO₂ sensors that respond to the detected variables by generating a voltage potential (which would be electrical detectable) that can be conducted to the memory device and recorded (column 38, lines 46-62). The recording itself would be permanently detectable. Nova et al further teach memory and recording devices such as EEPROMs (column 8, lines 55-60).

17. With respect to claims 5, 12-18, Nova et al teaches the use of radiation, pH, and PCO₂ sensors, which respond to the detected variables by generating a voltage potential that is conducted to the memory device and recorded.

Although the prior art do not specifically teach that the chemical concentrations comprise a pH of about 5 to about 9, or a salinity of about 0.01 molar to about 8 molar, or affects the target-probe interaction, these limitations do not have any patentable weight, as they refer to the chemical concentrations, which are not claimed by applicant. Since the sensors disclosed by the prior art would be capable of detecting chemical concentrations comprising a pH of about 5 to about 9, or a salinity of about 0.01 molar to about 8 molar, as well as changes in pH that would

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enhance or hinder target-probe interactions, the structural limitations of claims 12-18 would be fulfilled.

18. With respect to claims 19-22, 49-57, Nova et al teach a photodetector to record the occurrence of photo-emitting reactions (column 38, lines 33-38), including multianalyte immunoassays, receptor binding assays, hybridization reactions involving antibodies, nucleic acids, proteins, enzymes with fluorescent labels, radiolabels, luminophore labels, enzyme labels (column 43, lines 25-50).

Claims 52-56 recite limitations that further limit a condition, which do not have any patentable weight, as applicants are claiming the device, and not the condition to which the device is exposed. Since in the device taught by Nova et al teaches hybridization reactions (hybridization condition) between probes and target molecules occur, the prior art would read upon claims 52-56.

19. With respect to claim 23, Nova et al also teach the use of electromagnetic radiation representative of a data signal corresponding to an indicator (column 10, lines 58-65).

20. Claims 26-29 refer to an intended use of the device (exposing the indicator to a condition from a predetermined period), and therefore have not been given any patentable weight. In particular, claims 26-29 recite a method step of exposing the indicator to a condition for a period of time. Since Nova et al teach indicators that would be capable of exhibiting a response after exposure to a condition (column 6, lines 25-36, column 38, lines 46-62), the prior art would read upon claims 26-29.

21. With respect to claims 47, the device may be a microtiter plate (column 12, lines 60-63) with molecules and biological particles attached (column 14, lines 28-56)

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22. Claims 59-60 recite limitations that further limit the condition, which do not have any patentable weight, as applicants are claiming the device, and not the condition to which the device is exposed. Furthermore, the limitations appear to recite method steps in which the device claimed by applicant is made, which has no patentable weight in a product claim. Since the device taught by Nova et al can be exposed to a condition suitable or not suitable for attaching a plurality of molecular moieties to the substrate surface, the prior art would still read upon claims 59-60.

Claim Rejections - 35 USC § 103

IV. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al [US 5,874,214] and further in view of Rava et al [US 5,545,531].

With respect to claims 36-39, Nova et al teach nucleic acid probes linked to matrices with memories for screening in assays (column 47, lines 50-52), and that the amount of these particulate matrices with memories can exceed 10^{15} , and have sizes of 1 mm^3 or smaller (column 7, lines 1-3). Nova et al also teach that the matrices may comprise continuous surfaces such as microtiter plates with molecules and biological particles attached (column 12, lines 60-63). Nova do not teach that the array comprises specific number of probes such as 10, 50,000, 200,000, and 1,000,000 probes/ cm^2 substrate surface.

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Rava et al, however, teach the use of probe arrays with sizes of $.25 \text{ mm}^2$ having different amounts of addressable features (probes), including at least 100, 1,000, 100,000, and 1,000,000 addressable features (column 9, lines 10-26). Rava et al further teach that these arrays allow for much higher throughput of test samples, greatly improving the efficiency of performing assays on biological chips (column 4, lines 25-34). Therefore it would also have been obvious in the method of Nova et al to have arrays with different densities of probes, including at least 100, 1,000, 100,000, and 1,000,000 probes/ cm^2 substrate surface, as suggested by Rava et al, in order to improve the efficiency of performing assays on biological chips.

Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

24. No claims are allowed.

25. The following references are also cited as art of interest: Shuber [US 5,888,778], Nova et al [US 5,741,462].

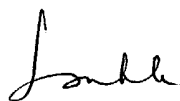
26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


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06/24/04